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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,356	03/26/2004	Joseph G. Furst	ICON 213110US03	1250

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EXAMINER	
BUI, VY Q	

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,356	FURST, JOSEPH G.	
	Examiner	Art Unit	
	Vy Q. Bui	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *89-94, 98-100, 104-108, 112-141* is/are pending in the application.

4a) Of the above claim(s) *91,94,99, 107,114,126,129,132,135-138 and 141* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date __.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims rejected are 89,90,92,93,98-100,104-106,108,112,113,115-125,127,128,130,131,133,134,139 and 140.

DETAILED ACTION

Election/Restrictions

Claims 91,94, 99, 107,114,126,129,132,135-138 and 141 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 133-134 are examined as requested by the Applicant (body treated with radiation). Election of the body member made of a biodegradable material was made **without** traverse in the reply filed on 6/3/2009.

Restriction is made final and withdrawn claims are required to be cancelled.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 89, 112, 124, 127 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hossainy et al.-6,287,628 B1 (Hossainy).

As to claims 89 and 112, Hossainy (C 8, L 12 to C9, L 20; C 11, L 57 to C 13, L 43; F 1-4B) discloses a stent 10 comprising pores or depots 22A, 22B (F 3A-3B) deposited with a therapeutic substance, such as a well known cystostatic biological agent for inhibiting cell growth and division **trapidil** (C 11, L 57 to C 13, L 43; F 1-4B), and a compound **taxol** in a third rinse fluid to form a coating of taxol on the outer surface of stent 10 (C 8, L 12 to C9, L 20). Hossainy (C 8, L 30 to C 9, L 20) also discloses a biodegradable materials, such as DL-PLA, L-PLA, in a third rinse fluid to form a polymeric coating impregnated with a therapeutic substance

for controlling the release rate of the therapeutic substances (in the polymeric coating and in the pores or depots 22A, 22B as shown in F 3A-3B). Alternatively, it would have been obvious to one of ordinary skill in the art to have a solution of a trapidil and the polymeric in the third rinse fluid so that a trapidil impregnated in the polymer coating is formed over stent 10.

As to claim 124, inherently stent 10 of Hossainy must remain substantially long enough to cover the treatment site after expansion.

As to claim 127, stent 10 has at least an outer smooth surface opposite to the depot openings.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 90, 92-93, 98-100, 105-106, 108, 113, 115-123, 125, 128, 139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al.-6,287,628 B1 (Hossainy) in view of Machan et al.-US2002/0065546 A1 (Machan).

As to claims 90, 92-93, 98-100, 105-106, 108, 113, 115-123, 125, 128, 139, Hossainy discloses stent 10 substantially as recited in the claims, except for a treatment compound GM-CSF and a biodegradable / ethylene acrylic acid as an intermediate compound. However, Machan et al.-US2002/0065546 A1 (Abstract; sections [0015], [0016], [0030]-[0032], [0046]-[0048], [0075], [0080] and claims 8, for example) discloses stent grafts including bioactive agent, such as a **GM-CSF** or microcrystals of monosodium urate monohydrate (see [0016], [0030]), or **taxol** (see [0046]), intermediate compound such as a biodegradable PLA/a PLGA-MePEG/a poly lactide co-glycolide (see [0015], [0031], [0048]) or ethylene acrylic acid, which is a hydrophobic and hydrophilic compound (see [0032]). It would have been obvious to one of

ordinary skill in the art to provide stent 10 of Hossainy the features taught by Machan, as the missing features are predictable to produce additional treatment results to the Hossainy stent 10. *KSR In't Co. V. Teleflex Inc. 127 S. Ct. 1727, 1741 (2007).*

Notice that as defined in the specification, the terms stent and graft are interchangeable (page 2, line 15), therefore, a stent and a graft are considered as the same or equivalent devices.

2. Claims 89, 130-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al.-6,287,628 B1 (Hossainy) in view of Machan et al.-US2002/0065546 A1 (Machan) and in view of Schwartz et al-6,368,658 B1 (Schwartz).

As to claims 130-131, Schwartz et al-6,368,658 B1 discloses coating a medical device, such as a catheter, a stent graft, a stent of a metal or a polymeric material (col. 3, line 41 to col. 4, line 14) with a radiopaque material for fuoroscopic visualization (col. 1, lines 13-33) and/or with a biodegradable polymer coating (col. 6, lines 37) including bioactive agents such as trapidil (col. 4, line 65), rapamycin (col. 4, line 37) or paclitaxel (col. 4, line 45) for a treatment at a body location. It would have been obvious to one of ordinary skill in the art to provide stent 10 of Hossainy with features taught by Machan and Schwartz, as the missing features are predictable to produce additional treatment results to the combination stent of Hossainy and Machan teaching. *KSR In't Co. V. Teleflex Inc. 127 S. Ct. 1727, 1741 (2007).*

3. Claims 133-134 and 140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al.-6,287,628 B1 (Hossainy) in view of Machan et al.-US2002/0065546 A1 (Machan) and further in view of Sirhan et al.-US2002/0082679 A1 (Sirhan).

As to claims 133-134 and 140, a stent (or graft) in view of Hossainy and Machan substantially discloses the claimed invention, except for the stent body is treated with Gamma

or Beta radiation. However, Sirhan (for example, Fig. 1C, sections [30], [0043], [0089], [0052], [0053], claims 18 and 126) discloses a medical device 16 having an intermediate compound/rate-controlling element 25 such as a parylene to control a releasing rate of a biological agent 28 such as GM-CSF or rapamycin, a radiopaque agent (see [section 0043]) and a radiation gamma treatment (see section [0070]) to treat a vascular site. It would have been obvious to one of ordinary skill in the art to provide a stent combination of Hossainy and Machan to have a gamma radiation as taught by Sirhan as this would be a proper treatment of a vascular site and the result is predictable to produce additional treatment results to the combination stent of Hossainy and Machan teaching. *KSR In't Co. V. Teleflex Inc. 127 S. Ct. 1727, 1741 (2007).*

Response to Arguments

Applicant's arguments filed in paper 1/15/20108 have been fully considered but they are moot in view of new grounds of rejection presented above.

Hossainy clearly teaches a combination of taxol and trapidil for a more effective treatment of a vascular site in comparison to just only trapidil.

Similarly, to provide an additional **well known treatment agent**s, such as rapamycin, GM-CSF, taxol, trapidil, to have a more effective treatment is predictable and it would have been obvious to one of ordinary skill in the art who know the treatment effects of a rapamycin or a GM-CSF or a trapidil or a taxol.

In the "Remarks", the Applicant stated that Schwartz (priority date 4/19/1999) is not a prior art because this present claimed invention has priority dates of patent application prior to the priority date of Schwatz . The Applicant is requested to provide evident that the claimed

subject matters in this present application were presented prior to the priority date (4/19/1999) of Schwatz. If the evident is provided, the rejection based on Schwartz will be withdrawn.

Conclusion

The claims have been amended (paper 1/15/2010) in response to the "Non-Final" rejection (paper 10/16/2009).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vy Q. Bui/
Primary Examiner, Art Unit 3773